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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known	
Application Number	09/974,781
Filing Date	10 October 2001
First Named Inventor	Michael G. Kahn
Group Art Unit	2166
Examiner Name	Unknown
Attorney Docket Number	FSTK 1004-1

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
DBC	C1	DataEdge LLC. Indexes of Clinical Study Complexity, 1993-1999. In: Mathieu MP, editor. Parexel's Pharmaceutical R&D Statistical Sourcebook 2000. Waltham, MA: Parexel International Corp; 2000. p. 66.	
DBC	C2	DataEdge LLC. Indexes of Clinical Trial Costs Per Patient, 1993-1999. In: Mathieu MP, editor. Parexel's Pharmaceutical R&D Statistical Sourcebook 2000. Waltham, MA: Parexel International Corp; 2000. p. 67.	
DBC	C3	GROSSO W. E. et al.; "Knowledge Modeling at the Millennium (The Design and Evolution of Protégé-2000)," SMI Report Number: SMI-1999-0801 (1999), available at http://smi-web.stanford.edu/ pubs/SMI_Abstracts/SMI-1999-0801.html, visited 01/01/2000.	
DBC	C4	HOLFORD N. H. G.; KIMKO H. C.; MONTELEONE J. P. R., and PECK C. C.; "Simulation of Clinical Trials," Annu. Rev. Pharmacol. Toxicol. 2000, 40:209-34, 2000, Annual Reviews.	
DBC	C5	"ICH Harmonised Tripartite Guideline: General Considerations for Clinical Trials," International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use recommended for adoption on 17 July 1997, URL: www.ifpma.org/ich5e.html, Accessed: 31 August 2001.	
DBC	C6	"ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice," International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use recommended for adoption on 1 May 1996 , URL: www.ifphma.org/ich5e.html, Accessed: 31 August 2001.	
DBC	C7	KROLL J. A.; DE BRUIN A.; GETZ K.; ESCHMANN K.; and ZISSON S.; "Study Conduct Delays are Getting Worse," In: Kroll JA, editor. An Industry In Evolution. Second ed. Boston, MA: CenterWatch; 1999. p. 99.	
DBC	C8	MUSEN M. A.; "Domain Ontologies in Software Engineering: Use of Protégé with the EON Architecture," Methods of Information in Medicine, F. K. Schattauer Verlagsgesellschaft mbH (1998); 37:540-50.	
DBC	C9	MUSEN M. A.; GENNARI J. H.; ERIKSSON H.; TU S. W.; and PUERTA A. R.; Protégé-II: Computer Support for Development of Intelligent Systems from Libraries of Components," MEDINFO 95 Proceedings. R. A. Greenes et al. (editors); 8(1):766-70.	
DBC	C10	MUSEN M. A.; ROHN J. A.; FAGAN L. M.; and SHORTLIFFE E. H.; "Knowledge Engineering for a Clinical Trial Advice System: Uncovering Errors in Protocol Specification," Report KSL-85-51, Proceedings AAMSI Congress 1986 (Levy, A.H. and Williams, B.T., eds.), pp. 24-27, Anaheim CA, May 1986.	
DBC	C11	SHEINER L. B. and STEIMER J. L.; "Pharmacokinetic/Pharmacodynamic Modeling in Drug Development," Annu. Rev. Pharmacol. Toxicol. 2000. 40:67-95, 2000, Annual Reviews.	

Examiner Signature	Dilelle S Cobaugh	Date Considered	02/26/2007

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DBC	C12	WAMPLER S., "Tackling Protocol Complexity," Good Clinical Practice Journal, 2000; Vol. 7, No. 2: pp. 6-8.	

Examiner Signature	Derek B Coborough	Date Considered	02/26/2007

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